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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/505,138	08/19/2004	Rango Dietrich	26230	1681
34375	7590	11/03/2006	EXAMINER	
NATH & ASSOCIATES PLLC 112 South West Street Alexandria, VA 22314			SILVERMAN, ERIC E	
		ART UNIT		PAPER NUMBER
				1615

DATE MAILED: 11/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/505,138	DIETRICH ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Eric E. Silverman, PhD	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### **Status**

1) Responsive to communication(s) filed on 01 August 2006.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### **Disposition of Claims**

4) Claim(s) 18 – 23, 25 – 67 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 18 – 23, 25 – 67 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### **Application Papers**

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### **Priority under 35 U.S.C. § 119**

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### **Attachment(s)**

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_

5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submissions filed on 6/1/2006 and 8/1/2006 have been entered. Claims 18 – 23, 25 – 67 are pending.

### ***Response to Arguments***

Applicant's arguments with respect to claims 18 – 23, 25 – 32, 37, and 58 – 65 have been considered but are moot in view of the new ground(s) of rejection.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 67 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim recites "Polyvidone K90". This appears to be a trade name. Trade names point out only the source of goods, not the nature of the goods themselves. It is suggested that this term be replaced with a generic name for the polyvinylpyrrolidone which applicants which to recite.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 18 – 23, 25 – 32, 36, 37, 58 – 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2003/0018071 to Rennard in view of US 6,677,362 to Ghebre-Sellassie et al., and in further view of US 4,024,240 to Thakkar.

Rennard teaches the PDE 4 inhibitor of instant claims, rolflumilast (paragraph 0015), in a tablet or capsule (paragraph 0020) and a method of administering same to an individual in amounts commensurate with those of instant claims (paragraphs 0021 – 0022). Rennard further teaches immediate release formulations of these drugs, which contain excipients such as lactose, microcrystalline cellulose, starch, and magnesium stearate (table 2).

Rennard does not teach polyvinylpyrrolidone.

The '362 patent teaches that drugs with low water solubility are advantageously combined with polyvinylpyrrolidone to increase the bioavailability of such drugs (abstract). The reference further teaches that any drug with some limited water solubility may be used.

Thakkar teaches the use of polyvinylpyrrolidone solid dosage forms (abstract, col. 1, examples). Polyvinylpyrrolidone having molecular weights between 10,000 and 360,000 is taught to be useful in such forms.

It would be prime facie obvious to a person of ordinary skill in the art at the time of the invention to use polyvinylpyrrolidone in the invention of Rennard. The motivation to do so comes from the '362 patent, which suggests this modification in order to

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increase the bioavailability of the drug. Although Rennard does not teach the molecular weights recited in instant claims, Thakkar notes that the range of polyvinylpyrrolidone molecular weights recognized as useful in pharmaceutical dosage forms includes all of the claimed polyvinylpyrrolidones. As such, it would be merely a matter of routine experimentation or optimization to find which polyvinylpyrrolidone achieved the best result.

Claims 33 – 35, and 38 – 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rennard, Ghebre-Sellasie, and Thakkar, as applied to claims 18 – 23, 25 – 32, 36, 37, 58 – 67 above, and in further view of Remington: The Science and Practice of Pharmacy, 1995.

The teachings of Rennard, Ghebre-Sellasie, and Thakkar are discussed above.

Rennard, Ghebre-Sellasie, and Thakkar are missing a teaching of corn starch and the granulation and related methods recited in instant claims.

Remington teaches that corn starch is a binder typically used in the tablet making art. Remington further teaches the various steps in granulation and related processes, as recited in instant claims, and that such steps are typical in the art of producing tablets.

It would be prime facie obvious to a person of ordinary skill in the art at the time of the invention to use corn starch as an additive in the invention of Rennard, Ghebre-Sellasie, and Thakkar, since such is well-known in the art as being useful for making tablets. With regard to the specific amounts of ingredients in the tablets, these are deemed to be merely the results of optimization and dosing of the active agent, which

the artisan is motivated to do in order to achieve the best result and to treat the condition of interest. With regard to the order of addition of the various ingredients, the artisan would recognize that in a granulation process, the ingredients can be added in the desired order in order to achieve the best result. As taught by Remington, the particular order can be varied as per the convenience of the practitioner.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric E. Silverman, PhD whose telephone number is 571 272 5549. The examiner can normally be reached on Monday to Friday 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571 272 8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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Art Unit 1615



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